

## Module: 8 Data for Abridged Applications and Specialised Products

Date: 19/05/2026 – 21/05/2026



**Location:** TOPRA Office: 3rd Floor, City Reach 5, Greenwich View Place, London, E14 9NN

**Module Leaders:** Alenka Dražumerič and Maša Kenda

**Day 1:** 19<sup>th</sup> May 2026

<b>Time</b>	<b>Activity</b>	<b>Speaker</b>
<b>08:45 – 09:00</b>	<b>Registration</b> <b>Welcome &amp; Introduction to the Module</b>	<b>Alenka Dražumerič</b> <b>Maša Kenda</b>
<b>09:00 – 10:00</b>	<b>Lecture 1: Revision of Regulatory Strategic Issues for Abridged Applications - A Regulatory Agency's Experience</b> Legal basis Definition of generics Intellectual property Regulatory procedures Paediatric regulation Submission strategy	<b>TBC</b>
<b>10:00 – 11:00</b>	<b>Lecture 2: CMC Drug Substance – Established Molecules</b> CEPs, DMFs Physicochemical properties Setting drug substance specification Manufacturing issues for drug substance Containers Stability requirements TSE Specific data requirements for other regions, i.e. LATAMA/APAC	<b>David Voglar,</b> Sandoz
<b>11:00 – 11:30</b>	<b>Refreshment Break</b>	
<b>11:30 – 12:30</b>	<b>Lecture 3: CMC Data Requirements: Drug Product</b> Line extension with different dosage forms Generics product development and manufacture Specifics of modified release, topical products, injections Setting drug product specification Stability requirements Common deficiencies Inspections Specific data requirements for other regions, i.e. LATAM/APAC	<b>Alenka Dražumerič,</b> O live D.A.
<b>12:30 – 13:30</b>	<b>Lunch</b>	
<b>13:30 – 14:30</b>	<b>Lecture 4: Bioequivalence</b> Pharmaceutical equivalence Therapeutic equivalence Design of bioequivalence studies Biowaiver Choice of reference and test products Review of the revised guideline on bioequivalence	<b>Dejan Krajcar,</b> Sandoz
<b>14:30 – 15:30</b>	<b>Lecture 5: Non-clinical Considerations: Abridged Applications and Testing Strategies</b> Bridging Tox Combination products Paediatric indications	<b>Michelle McDonald-</b> <b>Alexis,</b> Parexel

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Novel excipients  
Environmental Risk Assessment

**15:30 – 16:30 Lecture 6: Clinical considerations**

New Indications  
New Routes of Administration  
Additional dosage forms  
New target population  
Paediatric indications

**Rozeta Mileva-  
Peceva,**  
Acino International AG

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Day 2: 20<sup>th</sup> May 2026

Time	Activity	Speaker
08:45 – 9:00	<b>Introduction to Day 2 and review of Day 1</b>	<b>Alenka Dražumerič Maša Kenda</b>
09:00 – 10:00	<b>Lecture 7: Abridged Options US</b> Abbreviated NDAs Supplementary NDAs 505(b)(2) applications Influence of ICH in the US Role of the FDA and recent developments (i.e. fees, ObD)	<b>Sarah Roberts,</b> PRA International
10:00 – 11:00	<b>Lecture 8: Drug Device Combinations</b> Definition (Medicinal Product/Medical Device) Medical Device legislation Regulatory approval process Drug/Device products (borderline products, medicated devices, drug delivery systems, drug device combinations)	<b>TBC</b>
10:00 – 11:15	<b>Refreshment Break</b>	
11:15 – 13:00	<b>Case Study 1</b>	<b>Module Leaders</b>
13:00 – 14:00	<b>Lunch</b>	
14:00 – 15:00	<b>Lecture 9: Blood Products</b> What are blood products? Master files Albumin as an excipient	<b>Maša Kenda,</b> Octapharma
15:00 – 16:00	<b>Lecture 10: Inhalation Products</b> Product types (nebulisers, MDIs, DPIs) Quality/Safety/Efficacy Product information (SmPC, labelling)	<b>David Lawson</b> Ventus

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**Day 3:** 21<sup>st</sup> May 2026

<b>Time</b>	<b>Activity</b>	<b>Speaker</b>
<b>08:45 – 09:00</b>	<b>Introduction to Day 3 and Review of Day 2</b>	<b>Alenka Dražumerič Maša Kenda</b>
<b>09:00 – 10:00</b>	<b>Lecture 11: Radiopharmaceuticals</b> What are Radiopharmaceuticals? Examples of Radiopharmaceuticals use Radiopharmaceuticals legislation Manufacturing challenges Specifics of Quality/Non-clinical/Clinical data Product information (SmPC, labelling)	<b>Peter Bradley,</b> GE Healthcare
<b>10:00 – 11:00</b>	<b>Lecture 12: Herbals</b> Overview of legislation for herbals Registration routes: Well established use, traditional use Specific requirements for herbals: Quality, Safety, Efficacy	<b>Astrid Obmann,</b> AGES
<b>11:00 – 11:15</b>	<b>Refreshment Break</b>	
<b>11:15 – 13:00</b>	<b>Case Study 2:</b>	<b>Module Leaders</b>
<b>13:00 – 14:00</b>	<b>Lunch</b>	
<b>14:00 – 15:00</b>	<b>Lecture 13: Cosmetics</b> EU Requirements of the Cosmetic Regulation Ingredients & manufacture requirements Responsible Person & Product Information File Cosmetic Notification Labelling & Cosmetovigilance Cosmetic vs. Medicine – borderline issues	<b>Arun Mishra,</b> Unilever
<b>15:00 : 15:15</b>	<b>Close</b>	